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PATENT ABSTRACTS OF JAPAN

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(21)Application number : 09-130003 (71)Applicant : MENICON CO LTD

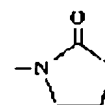
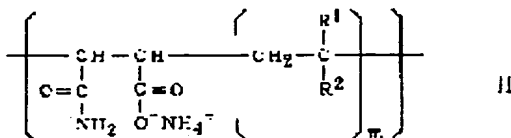
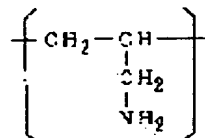
(22)Date of filing : 20.05.1997 (72)Inventor : NAKADA KAZUHIKO
MATANO HIROSHI

(54) DISTRIBUTING AND PRESERVING SOLUTION FOR CONTACT LENS AND METHOD FOR DISTRIBUTING AND PRESERVING CONTACT LENS USING THE SAME

(57)Abstract:

PROBLEM TO BE SOLVED: To suppress a change of the base curve of a contact lens at the time of wet preservation and distribution by incorporating a specified polyallylamine, its salt or a specified polymer.

SOLUTION: This distributing and preserving soln. contains ≥ 0.01 w/v%, preferably ≥ 0.1 w/v% at least one selected from among a polyallylamine having repeating units represented by formula I, a salt of the polyallylamine and a polymer represented by formula II, wherein R¹ is a group represented by formula III, 1-12C alkyl or a group represented by formula IV, R² is H or methyl and (m) is an integer of 1-5. In the formula IV, R³ is H or amino. The salt is, e.g. hydrochloride or acetate. The polymer is typically a half amide of a maleic anhydride copolymer obtd. by allowing the maleic anhydride copolymer to react with ammonia.



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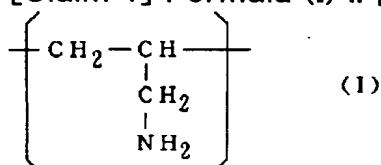
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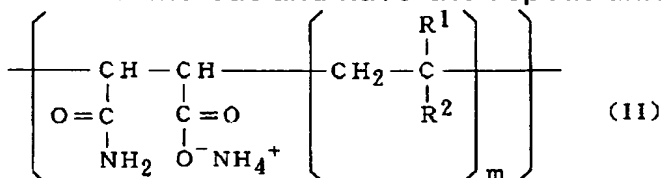
CLAIMS

[Claim(s)]

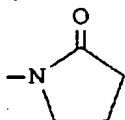
[Claim 1] Formula (I) : [Formula 1]



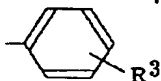
: The salt and general formula (II) of the poly allylamine and this poly allylamine which come out and have the repeat unit expressed [Formula 2]



(The inside of a formula and R1 are formula:) [Formula 3]



: The basis, the alkyl group of carbon numbers 1-12, or general formula come out of and expressed [Formula 4]



the basis expressed with (R3 shows a hydrogen atom or the amino group among a formula), and R2 — a hydrogen atom or a methyl group, and m — the integer of 1-5 — being shown — the circulation preservation liquid for contact lenses which comes to contain at least one sort of compounds chosen from the polymer which has the repeat unit expressed

[Claim 2] Circulation preservation liquid for contact lenses according to claim 1 whose content of a compound is 0.01 ~ 10 w/v%.

[Claim 3] Circulation preservation liquid for contact lenses according to claim 1 or 2 which comes to contain at least one sort of antiseptics and a chelating agent.

[Claim 4] The circulation store method of the contact lens characterized by making

a contact lens flood with the circulation preservation liquid for contact lenses according to claim 1, 2, or 3.

[Claim 5] The circulation store method according to claim 4 from which a contact lens carries out the polymerization of the polymerization component containing the silicon compound, and is obtained.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[The technical field to which invention belongs] this invention relates to the circulation store method of a contact lens which used the circulation preservation liquid for contact lenses, and it.

[0002]

[Description of the Prior Art] Generally, in a contact lens, especially an oxygen permeability hard contact lens, that the silicone component contains almost comes out, and for a certain reason, a lens front face becomes hydrophobic, and it becomes easy to generate the problem that the wettability at the time of initial wearing is bad, a feeling of wearing does not fall by this, or sufficient eyesight is not acquired.

[0003] Then, in order to hold the surface-water-of-aggregate wettability after being manufactured until a patient wears, surface treatment is performed, or the aforementioned oxygen permeability hard contact lens is beforehand flooded with circulation preservation liquid, such as a physiological saline, and wet preservation of it is carried out and it circulates.

[0004] However, when wet preservation circulation using such a physiological saline etc. is performed, in the circulation process, there is a problem that the base curve which is one of the important specification of a contact lens may change.

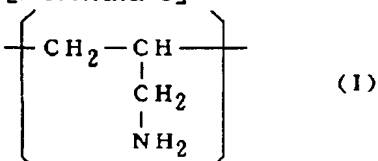
[0005]

[Problem(s) to be Solved by the Invention] this invention is made in view of the aforementioned conventional technology, and aims at offering the circulation store method of the contact lens using the circulation preservation liquid and it which can reduce change of the base curve remarkably at the time of wet preservation circulation of a contact lens, especially an oxygen permeability hard contact lens.

[0006]

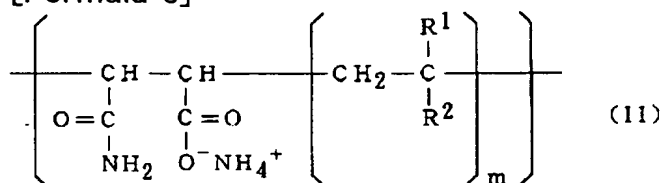
[Means for Solving the Problem] this invention is ** formula (I):. [0007]

[Formula 5]



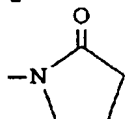
[0008] : The salt and general formula (II) of the poly allylamine and this poly allylamine which come out and have the repeat unit expressed [0009]

[Formula 6]



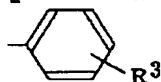
[0010] (The inside of a formula and R1 are formula:) [0011]

[Formula 7]



[0012] : The basis, the alkyl group of carbon numbers 1-12, or general formula come out of and expressed [0013]

[Formula 8]

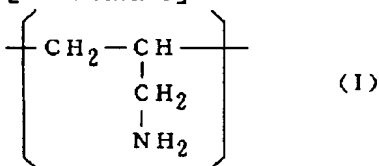


[0014] the basis expressed with (R3 showing a hydrogen atom or the amino group among a formula), and R2 -- a hydrogen atom or a methyl group, and m -- the integer of 1-5 -- being shown -- it is related with the circulation store method of the contact lens characterized by to make a contact lens flood with the circulation preservation liquid for contact lenses which comes to contain at least one sort of compounds chosen from the polymer which has the repeat unit expressed, and the circulation preservation liquid for the ** aforementioned contact lenses

[0015]

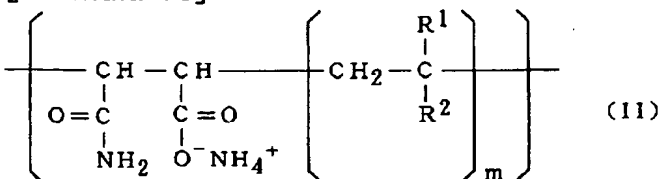
[Embodiments of the Invention] The circulation preservation liquid for contact lenses of this invention is formula (I): as described above. [0016]

[Formula 9]



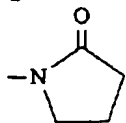
[0017] : The salt and general formula (II) of the poly allylamine and this poly allylamine which come out and have the repeat unit expressed [0018]

[Formula 10]



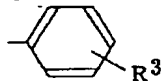
[0019] (The inside of a formula and R1 are formula:) [0020]

[Formula 11]



[0021] : The basis, the alkyl group of carbon numbers 1-12, or general formula come out of and expressed [0022]

[Formula 12]



[0023] the basis expressed with (R3 shows a hydrogen atom or the amino group among a formula), and R2 -- a hydrogen atom or a methyl group, and m -- the integer of 1-5 -- being shown -- at least one sort of compounds (henceforth a compound (A)) chosen from the polymer (henceforth polymer (A-1)) which has the repeat unit expressed are contained

[0024] In the circulation preservation liquid for contact lenses of this invention, in the poly allylamine and its salt, and a row, the compound (A) used as an active principle for reducing change of the base curve of a contact lens at the time of wet preservation circulation can be at least one sort of polymer (A-1), and, as for these, can be independent, or can mix two or more sorts in them, and it can use.

[0025] As an example of representation of the salt of the aforementioned poly allylamine, the hydrochloride of the poly allylamine, the acetate of the poly allylamine, etc. are raised, for example.

[0026] The weight average molecular weight of the poly allylamine or its salt In order to fully obtain the stabilization effect of the base curve of a contact lens When it takes into consideration that a certain amount of molecular weight is required, about [500 or more], It is desirable that they are about [1000 or more] preferably, and the solubility over media, such as water, falls. When a possibility that the uniform circulation preservation liquid for contact lenses may become is hard to be obtained arising, the problem of the handling nature by elevation of viscosity, etc. are taken into consideration, it is [about / 200000 or less] desirable that they are about / 100000 or less / preferably.

[0027] As an example of representation of the aforementioned polymer (A-1), for example, a maleic-anhydride copolymer is made to react with ammonia, and the so-called half AMAIDO of the maleic-anhydride copolymer in which the basis originating in this maleic anhydride carried out ring breakage to the ammonium salt of a carbamoyl group and a carboxyl group is raised.

[0028] After dissolving a maleic-anhydride copolymer in suitable solvents, such as toluene and benzene, first as a concrete synthetic method of dealing in the half flax id of the aforementioned maleic-anhydride copolymer as indicated by the U.S. Pat. No. 2,746,837 specification, for example, anhydrous ammonia can be blown and the method of making a maleic anhydride the half flax id etc. can be adopted.

[0029] As an example of the aforementioned maleic-anhydride copolymer, poly (ethylene-maleic anhydride), poly (styrene sulfonic-acid-maleic anhydride), poly (butadiene-maleic anhydride), poly (styrene-maleic anhydride), etc. are raised, for

example.

[0030] In order to fully obtain the stabilization effect of the base curve of a contact lens, the weight average molecular weight of polymer (A-1) When it takes into consideration that a certain amount of molecular weight is required, about [500 or more], It is desirable that they are about [1000 or more] preferably, and the solubility over media, such as water, falls. When a possibility that the uniform circulation preservation liquid for contact lenses may become is hard to be obtained arising, the problem of the handling nature by elevation of viscosity, etc. are taken into consideration, it is [about / 100000 or less] desirable that they are about / 50000 or less / preferably.

[0031] The content in the circulation preservation liquid for contact lenses of the aforementioned compound (A) In order to make the effect of reducing change of the base curve of the contact lens at the time of the wet preservation circulation by having used this compound (A) fully discover It is desirable a 0.01 w/v% not less and that it is more than 0.1 w/v% preferably. moreover -- in order to abolish a possibility that a handling problem -- the viscosity of the circulation preservation liquid for contact lenses rises too much, and a contact lens becomes easy to become dirty at the time of dryness -- may arise -- 10 -- it is desirable that it is less than [3w/v%] preferably w/v% or less

[0032] In the circulation preservation liquid for contact lenses of this invention, it is desirable that antiseptics, the chelating agent, etc. contain other than the aforementioned compound (A).

[0033] The aforementioned antiseptics have the property to prevent that prevent the circulation preservation liquid for contact lenses being polluted by bacteria, and a contact lens is polluted with various germs at the time of circulation preservation.

[0034] antiseptics -- ophthalmology -- although there is especially no limitation that what is necessary is just what can be permitted physiologically -- as the example of representation -- mercury system antiseptics; benzalkonium chlorides, such as phenylmercuric nitrate, phenylmercuric acetate, and a thimerosal, and bromination -- alcoholic system antiseptics; methylparaben, such as surfactant system antiseptics; chloro HEKISHIJIN, such as pyridinium, a polyhexamethylene biguanide, and a chlorobutanol, a propylparaben, a dimethylol dimethylhydantoin, an imidazolium urea, etc. are raised

[0035] The content in the circulation preservation liquid for contact lenses of the aforementioned antiseptics In order to make sufficient antiseptics effect discover, more than 0.00001 w/v% Desirably [that it is more than 0.00003 w/v% preferably], when there are too much many contents of these antiseptics Since a possibility of doing an obstacle to an eye comes to arise or there is an inclination which a possibility of having a bad influence on the specification and the property of a contact lens comes to produce depending on the kind of antiseptics when these antiseptics go into a direct eye It is desirable a 0.5 w/v% less or equal and that it is less than [0.3 w/v%] preferably.

[0036] It has the property to prevent the calcium contained in the circulation preservation liquid for contact lenses or adhering tear fluid carrying out the deposition of the aforementioned chelating agent to a contact lens.

[0037] That a chelating agent should just be what can be permitted on an ophthalmology physiology target, although there is especially no limitation, as the example of representation, ethylenediaminetetraacetic acid and its sodium salt, a phytic acid, a citric acid, etc. are raised, for example.

[0038] The content in the circulation preservation liquid for contact lenses of the aforementioned chelating agent In order to make the effect which prevents calcium etc. carrying out deposition to a contact lens fully discover Desirably [that 0.001 mols /or more are / l. / 0.0015 mols/l. or more preferably], when there are too much many contents of this chelating agent improvement in the effect by making it contain more than it is small, and since it becomes rather uneconomical, what 0.1 mols /or less are [l.] 0.05 mols/l. or less preferably is desirable

[0039] Furthermore, in the circulation preservation liquid for contact lenses of this invention, compounding agents other than the aforementioned antiseptics and a chelating agent, such as shock absorbing material, an isotonizing agent, and a thickener, may contain.

[0040] The aforementioned buffer fixes pH of the circulation preservation liquid for contact lenses obtained in [near tear fluid] about five to nine, and stops the change of pH by the external factor, and has the property to protect the configuration of the contact lens at the time of circulation preservation, and the optical character.

[0041] That a buffer should just be what can be permitted on an ophthalmology physiology target, although there is especially no limitation, as the example of representation, a boric acid, the sodium salt and a phosphoric acid, the sodium salt and a citric acid, the sodium salt and a lactic acid, amino acid, such as the sodium salt, a glycine, and glutamic acid, the sodium salt and a malic acid, its sodium salt, etc. are raised, for example.

[0042] The content in the circulation preservation liquid for contact lenses of the aforementioned buffer In order to make sufficient buffer effect give, 0.005 mols/l. or more Desirably [that it is 0.01 mols/l. or more preferably], when there are too much many contents of this buffer Since there is an inclination which comes to affect the configuration of a contact lens -- a buffer effect does not become not much high, but raises osmotic pressure on the contrary -- it is desirable for 0.5 mols /or less to be [l.] 0.15 mols/l. or less preferably.

[0043] The aforementioned isotonizing agent brings the osmotic pressure of the circulation preservation liquid for contact lenses obtained close to the osmotic pressure (280 to 300 mOs/kg) of tear fluid, and has the property to make it the configuration of a contact lens become is easier to be maintained at the time of circulation preservation.

[0044] That an isotonizing agent should just be what can be permitted on an ophthalmology physiology target, although there is especially no limitation, as the example of representation, mineral salt and the aforementioned buffers, such as a sodium chloride, potassium chloride, and a calcium chloride, are raised, for example.

[0045] Since the content in the circulation preservation liquid for contact lenses of the aforementioned isotonizing agent comes to affect [tend] the configuration of a contact lens by osmotic pressure becoming high desirably [that 0.01 mols /or

more are / l. / 0.05 mols/l. or more preferably] when there are too much many contents of this isotonicizing agent in order to make sufficient osmotic pressure give, it is desirable for 0.5 mols /or less to be [l.] 0.15 mols/l. or less preferably.

[0046] The aforementioned thickener has the property to protect a contact lens from the physical force from the outside at the time of circulation preservation.

[0047] Although there is especially no limitation, that a thickener should just be what can be permitted on an ophthalmology physiology target as the example of representation For example, polyvinyl alcohol, Poly N vinylpyrrolidone, a polyacrylamide, and its hydrolyzate, A polyacrylic acid, xanthan gum, a hydroxyethyl cellulose, a carboxymethyl cellulose, Viscous bases, such as a methyl hydroxyethyl cellulose, methyl hydroxypropylcellulose, a methyl cellulose, a sodium alginate, a polyethylene glycol, gelatin, sodium chondroitin sulfate, gum arabic, and girl gum, are raised.

[0048] in order for the content in the circulation preservation liquid for contact lenses of the aforementioned thickener to make a contact lens fully protect from external stress at the time of circulation preservation — 0.01 — since there is w/v % or more of inclinations for the circulation preservation liquid for contact lenses obtained to gel, and for circulation shelf life to fall when [with desirable and it being more than 0.02 w/v% preferably] there are too much many contents of this thickener — 10 — it is desirable that it is less than [5w/v%] preferably w/v% or less

[0049] In addition, the aforementioned antiseptics, a chelating agent, a buffer, an isotonicizing agent, and a thickener are independent respectively, or two or more sorts can be mixed and used for them.

[0050] As the circulation preservation liquid for contact lenses of this invention was described above, although a compound (A) is contained as an active principle and components, such as antiseptics, a chelating agent, and other compounding agents, are contained further if needed, water, such as distilled water and a purified water, etc. should just be blended as these media. In addition, as the whole quantity of the circulation preservation liquid for contact lenses becomes 100%, it should just use aqueous media, such as this water.

[0051] A compound (A) can be put in into the aqueous medium of the specified quantity, and compounding agents, such as antiseptics, a chelating agent, a buffer, an isotonicizing agent, and a thickener, can be put in further if needed, and mixed churning is fully carried out, it can be made to be able to dissolve, and the circulation preservation liquid for contact lenses of this invention can be prepared by filtering.

[0052] In addition, although there is no limitation especially in the viscosity of the circulation preservation liquid for contact lenses of this invention, when the handling nature at the time of carrying out circulation preservation of the contact lens etc. is taken into consideration, it is desirable that they are about 200 or less cPs at 25 degrees C.

[0053] Moreover, as for pH of the circulation preservation liquid for contact lenses, it is desirable that it is 5–9 of the same grade as pH of tear fluid.

[0054] By making a contact lens flood with the circulation preservation liquid for contact lenses of this invention obtained in this way, circulation preservation of the

various contact lenses can be carried out, without changing most of the base curve.

[0055] In addition, what is necessary is to put in and seal a contact lens and the aforementioned circulation preservation liquid for contact lenses of an amount in which this contact lens is immersed and it deals, for example in a predetermined container, and just to carry out circulation preservation in the circulation store method of the contact lens of this invention.

[0056] Moreover, although there is no limitation especially in the contact lens used for the circulation store method of this invention and what kind of thing can also be applied irrespective of water nature, non-water nature and elasticity, and hard Especially, for example A siloxanyl (meta) acrylate system monomer, Even if it is the case of the oxygen permeability hard contact lens which was made to carry out the polymerization of the polymerization component containing silicon compounds, such as a siloxanyl styrene system monomer, siloxanyl fumarate, and siloxanyl itaconate, and was obtained At the time of wet preservation circulation, change of the base curve is reduced remarkably.

[0057]

[Example] Although the circulation store method of a contact lens which used the circulation preservation liquid for contact lenses of this invention and it is further explained to a detail below based on an example, this invention is not limited only to this example.

[0058] The compound (A) shown in one to example 5 table 1 is added to distilled water, it agitated for about 60 minutes, the compound (A) was dissolved [it was a room temperature, or], warming a little, this was filtered further, and the content of a compound (A) prepared 300ml of 1w/v% of circulation preservation liquid for contact lenses.

[0059] The solubility, the appearance, the odor, pH, and viscosity of the obtained circulation preservation liquid for contact lenses were investigated according to the following methods. The result is shown in Table 2.

[0060] (b) The existence of the insoluble matter in the circulation preservation liquid for soluble contact lenses was investigated visually, and it evaluated based on the following error criteria.

[0061] (Error criterion)

A: There is no insoluble matter.

B: Insoluble matter is accepted slightly.

C: Insoluble matter is remarkable.

[0062] (b) The appearance of the circulation preservation liquid for appearance contact lenses was observed visually, and it evaluated based on the following error criteria.

[0063] (Error criterion)

A: It is transparent at homogeneity.

B: It is slightly cloudy.

C: Nebula is remarkable.

[0064] (c) From the distance of 5cm of odors, the odor of the circulation preservation liquid for contact lenses was investigated, and it evaluated based on the following error criteria.

[0065] (Error criterion)

A: There is no odor.

B: An odor is accepted slightly.

C: An odor is remarkable.

[0066] (d) pH of the 25-degree C circulation preservation liquid for contact lenses was measured in pH glass-electrode type pH meter (HORIBA pH METER F-13, Horiba Make).

[0067] (e) The viscosity (cP) of the 25-degree C circulation preservation liquid for contact lenses was measured in the viscosity Brookfield viscometer.

[0068] It fabricated, after carrying out copolymerization of the polymerization component which consists of the siloxanyl methacrylate 50 weight section, the trifluoroethylmethacrylate 40 weight section, the methyl methacrylate 10 weight section, and the ethylene glycol dimethacrylate 5 weight section next, and the oxygen permeability hard contact lens with a thickness of 0.12mm was manufactured.

[0069] Every five sheets of this oxygen permeability hard contact lens were prepared about each circulation preservation liquid for contact lenses obtained in the examples 1-5, and each base curve was measured beforehand.

[0070] Next, put the aforementioned oxygen permeability hard contact lens and the circulation preservation liquid for contact lenses into the circulation case for contact lenses, and this oxygen permeability hard contact lens was made to flood with the circulation preservation liquid for contact lenses, and it sealed, and saved at 40 degrees C, and each base curve was measured after two weeks and four weeks.

[0071] The variation of a base curve was calculated from the difference of the base curve after preservation, and the base curve measured beforehand, the average variation of five contact lenses was computed and the rate of change (%) of a base curve was calculated from the average of the base curve of five contact lenses before preservation based on the following formulas. The result is shown in Table 2.

[0072] Rate-of-change (%) = [(average variation of base curve) / (average of base curve before preservation)] x 100 of a base curve. [0073] The physiological saline was used instead of the circulation preservation liquid for contact lenses of example of comparison 1 examples 1-5, and it asked for the rate of change of a base curve like examples 1-5. The result is shown in Table 2.

[0074] Instead of 1w/v% in example 6 examples 1-5 of each compound (A), example number [which is shown in Table 1 / (Compound A) 0.5 w/v% of] 6, Polly N vinylpyrrolidone (30k) 0.5 w/v%, and polyhexamethylene biguanide 1ppm (weight) and ethylenediaminetetraacetic acid 1w/v% (0.033 mols/(l.)) were used, and also make it be the same as that of examples 1-5. 300ml of circulation preservation liquid for contact lenses was prepared.

[0075] The solubility, the appearance, the odor, pH, and viscosity after the obtained circulation preservation for contact lenses were investigated like examples 1-5. The result is shown in Table 2.

[0076] Moreover, it asked for the rate of change of a base curve like examples 1-5 using the aforementioned circulation preservation liquid for contact lenses. The

result is shown in Table 2.

[0077]

[Table 1]

表 1

実施例 番 号	化合物 (A) の種類
1	ポリ(エチレン-無水マレイン酸)のハーフアמיד(エチレン/無水マレイン酸(重量比):1/1、重量平均分子量:3000)
2	ポリ(スチレンスルホン酸-無水マレイン酸)のハーフアמיד(スチレンスルホン酸/無水マレイン酸(重量比):3/1、重量平均分子量:3500)
3	ポリ(ブタジエン-無水マレイン酸)のハーフアמיד(ブタジエン/無水マレイン酸(重量比):1/1、重量平均分子量:6000)
4	ポリ(スチレン-無水マレイン酸)のハーフアמיד(スチレン/無水マレイン酸(重量比):1/1、重量平均分子量:1500)
5	ポリアリルアミン (重量平均分子量:約10000)
6	ポリアリルアミン (重量平均分子量:約10000)

[0078]

[Table 2]

表 2

実施例 番 号	コンタクトレンズ用流通保存液の特性					コンタクトレンズのベース カーブの変化率 (%)	
	溶解性	外観	臭気	pH	粘度 (cP)	2週間後	4週間後
1	A	A	A	6.5	50 ≥	0.1	0.3
2	A	A	B	7.5	50 ≥	0.1	0.3
3	A	A	B	7.2	50 ≥	0.1	0.3
4	A	A	A	7.0	50 ≥	0.1	0.3
5	A	A	A	7.2	50 ≥	0.1	0.2
6	A	A	A	7.2	50 ≥	0.1	0.2
比較例 1	—	—	—	—	—	0.4	0.6

[0079] It turns out that it is what each circulation preservation liquid for contact lenses obtained from the result shown in Table 2 in the examples 1-6 has suitable pH and suitable viscosity, excels [liquid] in solubility and appearance, and it does not have an odor, or is not almost.

[0080] Moreover, of course, when a contact lens is saved using the circulation preservation liquid for contact lenses obtained in the examples 1-6 and it saves for

two weeks compared with the case where the physiological saline of the example 1 of comparison is used, even if it is a time of saving for four weeks, it turns out that the rate of change of the base curve of a contact lens is remarkably small all.

[0081]

[Effect of the Invention] If the circulation preservation liquid for contact lenses of this invention is excellent in solubility and appearance, and does not almost have an odor and wet preservation circulation of a contact lens, especially an oxygen permeability hard contact lens is performed using this circulation preservation liquid for contact lenses, change of the base curve which is one of the important specification of a contact lens will be reduced remarkably.

[Translation done.]